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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,491	10/14/2003	Rossella G. Tupler	07917-180001 / UMMC 03-18	3543

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P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
STANDLEY, STEVEN H	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,491	TUPLER ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *114/13/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10,11 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/04 & 9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7, and new claims 21-23 in the reply filed on 11/13/06 is acknowledged. Applicant further elected the species FRG1. The traversal is on the grounds that the generic claims to 4q35 region of chromosome 4 encompass the elected species. This is found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Priority is to the provisional application 60/418,024, filed 10/11/02.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and /or amino acid sequences set forth in 37 CFR 1821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that each sequence disclosed must appear separately in the sequence listing and in the text of the description and claims whenever described. For example, a SEQ ID NO: and sequence listing is required for the nucleic acid sequence shown in Figure 2C of the drawings. For instance, the SEQ ID NO: may be referenced in the "Brief Description of Drawings." See MPEP 2422 & 2431. This is not meant to be an exhaustive list of places where the specification fails to comply with th sequence rules. The specification has not been checked to the extent necessary to determine th epresence of all possible mior errors. Applicant's cooperation is requested in correcting any errors of which applicant may

become aware in the specification. The application cannot issue unless it is in compliance. Correction is required.

Information Disclosure Statement

3. The IDS' of 12/02/04 and 9/16/05 have been considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7, 10-11 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing a D4Z4 binding element ***with a specific sequence*** localized in region 4q35 of human chromosome 4, contacting the D4Z4 binding element with a test compound and determining whether the test compound interacts with the D4Z4 binding element, does not reasonably provide enablement for providing "a D4Z4 binding element," contacting the D4Z4 binding element with a test compound and determining whether the test compound interacts with the D4Z4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Further, the specification is not enabling for determining the level of expression of recited ***genes***, generic genes or named.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The invention is highly complex because it is not known just what constitutes "a D4Z4 binding element" from the specification or the prior art. The specification provides a circular, open-ended, structurally open definition on page 3, wherein "providing a D4Z4 binding element, e.g., DNA comprising one or more D4Z4 repeats," constitutes the only limitation to the DNA structure. Also, the specification teaches that, "D4Z4 is highly polymorphic with a variable number tandem repeat (VNTR) structure D4Z4." This definition imports little structural limitation to the D4Z4 binding element. Further, the specification discloses a 27 bp "minimal binding element." However, it is not known if the D4Z4 element comprises one or some defined number of ***exact*** repeats of this element, or whether this "minimal binding element" is loosely repeated in a D4Z4 binding element. It is not known from the specification what constitutes the structural limits of a D4Z4 binding element, nor what are the essential features of the D4z4 binding element. Therefore one skilled in the art would not recognize a D4Z4 binding element as recited in the claims and defined in the specification.

The prior art recognizes species variations in the sequences of the D4Z4 repeats (see Winokur et al., 1996), as well as D4Z4 repeats on all acrocentric chromosomes which include chromosomes 14, 15, 21 and 22. A blast analysis of a large fragment of the d4z4 repeat unit (accession D38024; appendix a; also see Lyle et al, 1995) shows divergence from the sequence in chromosome 10 (appendix b), indicating that 1) the

sequences are different, and 2) D4Z4 domains on the other acrosomal chromosomes listed above are divergent. Further, a blast of multiple copies of the "minimal binding element," as it relates to claim 23 for instance, against human genomic sequence yielded no sequence homology to anything. Therefore, at best the art and the specification give only an open-ended definition of D4Z4 that lacks structural boundaries. The art and the specification recognize an open ended, wide range of deletions or rearrangements, or repeats as, as well as plainly describing it as a highly variable region. Furthermore, claims 2-7 are directed to a D4Z4 binding element in a cell that expresses 4Q35, which does not mean the D4Z4 element must be the one localized on 4q35. Thus, the method measures the binding to elements that have nothing to do with 4q35, and nothing to do with expression of genes in that region.

The art (in this case, post filing date) indicates many other genes in the region of 4q35 (Blair et al, 2005) than are described in the disclosure or in the prior art. See Table I, Blair et al. Thus, the specification could not have been enabling for a generic "4q35 gene" at the time of filing. The claims also recite measuring expression of FSHD region ***genes***, such as FRG1, etc. However there is no description of such genes, their introns/exons, splice sites, promoter regions, and spice forms. Therefore one skilled in the art would not know what is being measured nor how to measure it.

Given the variance across species, the existence of multiple D4Z4 regions throughout the genome, and the lack of apparent homology to the putative minimal binding element, what constitutes a D4Z4 domain is highly unpredictable.

The breadth of the claims is such that they encompass D4Z4 regions unrecognizable to one skilled in the art.

Given the complex nature of the invention, the unpredictability of the art, the lack of adequate teachings or examples in the specification, and the breadth of the claims, one skilled in the art would not know how to make or use the invention as claimed.

5. Claims 1-7, 10-11 and 21-23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method of identifying compounds by using a generic D4Z4 binding element, a generic 4q35 gene, and FRG1, FRG2, and ANT1 ***genes.*** However, the specification lacks a closed structural definition of such things. Moreover, these elements are not known in the art (as demonstrated above). One skilled in the art would not recognize such. No written description is provided in the instant specification as to what structurally constitutes nucleotide sequences "...comprising D4Z4 binding elements or 4q35 genes", the boundaries and functional elements of which would be unknown to one skilled in the art at the time the invention was made. The specification has not described, nor can it be reasonably visualized by one skilled in the art, the structural and functional elements attributable to chromosome 4, which represents the boundaries of the nucleotide sequences as currently claimed. For example,

chromosome 4 contains other undescribed promoters, coding regions, 5' and 3' flanking regions, exons and introns, each with their own unique structure and function that is not described in the instant specification. In short, a D4Z4 binding element and 4q35 region, as written, are readable on the whole of chromosome 4, as well as other chromosomes. FRG1, FRG2, and ANT1 ***genes*** have undescribed promoters, coding regions, 5' and 3' flanking regions, introns and exons, each with their own unique structure and function that is not described in the specification.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of structures claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers* v. *Revel*, 25 USPQ2d 1601 at 1606 (CMC 1993) and *Amgen Inc.* v. *Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Winokur et al (1996).

Winokur et al provides a D4Z4 binding element (which is in a human lymphoblast; Figure 1, page 1568), contacts that element with DNA that hybridizes to the end of chromosme 4 (cosmid 88F8), which is contiguous with the D4Z4 binding element (see Figure 1). Thus, the test compound (DNA) interacts with the D4Z4 binding element. Steps (a)-(c) are accomplished by Winokur et al. Step (d) imports no limitations on the compound selected (i.e., the compound could be any compound); and step (d) necessarily flows from step (c) when the compound interacts with D4Z4. In other words, step (d) is inherently accomplished with the practice of steps (a)-(C) because "selecting the test compound as a candidate..." is accomplished when it is determined that a test compound interacts with D4Z4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
1/25/07

DAVID S. ROMEO
PRIMARY EXAMINER

1: D38024. Reports Homo sapiens FSHD...[gi:871846] Links

Features Sequence

```
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ACCESSION   D38024
VERSION     D38024.1  GI:871846
KEYWORDS    .
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
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REFERENCE   1  (bases 1 to 3303)
  AUTHORS   Lee,J.H., Goto,K., Matsuda,C. and Arahata,K.
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  JOURNAL   Muscle Nerve 2, S6-S13 (1995)
   PUBMED   7739628
REFERENCE   2  (bases 1 to 3303)
  AUTHORS   Lee,J.
  TITLE     Direct Submission
  JOURNAL   Submitted (22-AUG-1994) Je Hyeon Lee, National Institute of
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Query start position Sub

Features flanking this part of subject sequence:
226 bp at 5' side: similar to double homeobox 4c
1277 bp at 3' side: similar to double homeobox 4c

Score = 739 bits (384), Expect = 0.0
Identities = 513/555 (92%), Gaps = 35/555 (6%)
Strand=Plus/Plus

```
Query  1        ggtaccagcaggtgggccgcctactgcgcacgcgcgggtttgcgggcagccgcctgggct  60
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  1751312  GGTACCAGCAGGTGGGCCGCCTACTGCGCACGCGCGGGTTTGCGGGCAGCCGCCTGGGCT  175137

Query  61       gtgggagcagcccgggccagagctctcctgcctctccaccagcccaccccgccgcctgac  120
                |||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||
Sbjct  1751372  GTGGGAGCAGCCCGGGC-AGAGCTCTCCTGCCTCTCCACCAGCCCACCCCGCCGCCTGAC  175143

Query  121      cgccccctccccaccccccaccccccaccccggaaaacgcgtcgtccccctgggctgggt  180
                |||||||||||||||||| ||||||| ||||||||||||||||||||||||||||||||
Sbjct  1751431  CGCCCCCTCCCCACCCCC-ACCCCCCGCCCCCGGAAAACGCGTCGTCCCCTGGGCTGGGT  175148

Query  181      ggagacccccgtcccgcgaaacaccgggcccccgcgcagcgtccgggcctgacaccgctcc  240
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  1751490  GGAGACCCCCGTCCCGCGAAACACCGGGCCCCGCGCAGCGTCCGGGCCTGACACCGCTCC  175154

Query  241      gcccgctcgcctcctcctgtcgcccccgggccaccgtcgcccgcccgcccgggcccctgc  300
                | |||||||||||||| || |||||||| ||||||||||||||||||||||||||||||
Sbjct  1751550  GGCGGCTCGCCTCCTC-TG-CGCCCCCGCGCCACCGTCGCCCGCCCGCCCGGGCCCCTGC  175160

Query  301      gggcccctgcagccgcccagctgccagcacgg-gcggctggcggcggaacgcagacccCCA  359
                          |||||||||| |||||||||| ||| ||||||||||||||||||||||
Sbjct  1751608  ----------AGCCGCCCAGGTGCCAGCACGGAGCGCCTGGCGGCGGAACGCAGACCCCA  175165

Query  360      GGCCCGGCGCACACCGGGGACGCTGAGCGTTCCAGGCGGGAGGGAAGGCGGGCAGAGATG  419
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  1751658  GGCCCGGCGCACACCGGGGACGCTGAGCGTTCCAGGCGGGAGGGAAGGCGGGCAGAGATG  175171

Query  420      GAGAGAGGAACGGGAGAGACTAGAGGGGCGGA----------AGGGACGTTA-------  461
                |||||||||||||||  ||||||||||||          |||||||||
Sbjct  1751718  GAGAGAGGAACGGGAGA-CCTAGAGGGGCGGAAGGATGGGCGGAGGGACGTTAGGAGGGA  175177

Query  462      -GGAGGGAGGCAGGGAGGCAGGGAGGCAGGGAGGAACGGAGGGAGAGACAGAGCGACGCA  520
                 |||||||||||||||||||||||||||||||||||||||||| ||||||||||||||
Sbjct  1751777  GGGAGGGAGGCAGGGAGGCAGGGAGGCAGGGAGGAACGGAGGGAAAGACAGAGCGACGCA  175183

Query  521      GGGACTGGGGGCGGG  535
                |||||||||||||||
Sbjct  1751837  GGGACTGGGGGCGGG  1751851
```